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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,507	12/08/2000	Hong Wang	4810-56910	2417

7590 11/05/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/733,507	WANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-15, 18, 20-22 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-15, 18, 20-22 and 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

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### **DETAILED ACTION**

The Amendment filed August 4, 2003 has been entered.

Claims 2-5, 13, 15 and 20 are currently amended.

Claims 28-33 are newly added.

Claims 10, 16-17, 19 and 23-26 are cancelled.

Claims 1-9, 11-15, 18, 20-22 and 27-33 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Information Disclosure Statement***

Initialed and dated copies of Applicant's IDS forms 1449, filed March 20, 2003 and April 14, 2003, are attached to the instant Office action.

### ***Claim Rejections - 35 USC § 112***

Claims 1-9, 11-15, 18, 20-22 and 27 remain rejected, and newly added claims 27-33 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

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Applicant argues that while the pending claims have been restricted to a single species, a full spectrum of plant cyclin-dependent kinase inhibitors is disclosed (ICK1, ICK2, ICN2, ICN6 and ICN7), and that a consensus sequences is provided in figure 7. Applicant additionally points to the Written Description Guidelines which indicate that an actual reduction to practice is only one of several ways by which an Applicant may show possession, and that an actual reduction to practice of every species within a claimed genus is not required. Applicants also point out that the specification discloses an actual reduction to practice for each of the CDK inhibitors disclosed. Applicant additionally points to Example 18 of the Written Description Training Materials which illustrates that an actual reduction to practice of even a single species may adequately support the description of a relevant genus. Applicant additionally argues that the Examiner's general allegations of unpredictability do not establish a prima facie case that the written description requirement has not been met (reply pages 8-9).

Applicant's traversals have been carefully considered but are unpersuasive for the following reasons. The disclosed cyclin-dependent kinase inhibitors ICK1, ICK2, ICN2, ICN6 and ICN7 were all obtained from a single plant species (*Arabidopsis*), and thus do not constitute a representative number of species describing all plant cyclin-dependent kinase inhibitors. Furthermore, the rejected claims recite no structural limitations that identify a cyclin-dependent kinase inhibitor as an ICK1 cyclin-dependent kinase inhibitor, or as an *Arabidopsis* cyclin-dependent kinase inhibitor, or as a plant cyclin-dependent kinase inhibitor. With respect to the consensus sequence provided in figure 7, the Office notes that the rejected claims also make no reference to said consensus sequence. With respect to Applicant's disclosure of an actual reduction to practice, the Office maintains that the disclosed actual reduction to practice does not

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support the description of the broadly claimed genus because only a limited number of plant CDK inhibitors were actually reduced to practice, and because the specific phenotypic effects of only one plant CDK inhibitor (ICK1) are described. The Office also disagrees that a prima facie case that the written description requirement has not been met, as the rejection was not predicated on any allegation of unpredictability. The rejection at page 3 of the office action mailed September 10, 2002 was predicated on Applicant's failure to describe a substantial portion of the genus that comprises a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide that functions to modify development when expressed in a transformed plant.

Claims 1-9, 11-15, 18, 20-22 and 27 remain rejected, and newly added claims 28-33 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of modifying floral development of a plant by transforming a plant with a nucleic acid of SEQ ID NO:1 encoding the *Arabidopsis* cyclin-dependent kinase inhibitor ICK1, wherein the cyclin-dependent kinase inhibitor ICK1 is expressed in petal and stamen primordia to inhibit floral development, does not reasonably provide enablement for a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor, wherein the cyclin-dependent kinase inhibitor is expressed in proliferative tissue to inhibit development of a differentiated tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed September 10, 2002.

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Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that undue experimentation would not be required to practice the full scope of the claimed invention, as any experimentation needed to select optimal embodiments would be merely routine. Applicant also points out that a description of all embodiments is not required to satisfy the statutory requirement for an enabling disclosure (reply pages 10-11).

The Office acknowledges that all embodiments need not be exemplified in order to satisfy the statutory requirement for an enabling disclosure, but maintains that the instant disclosure does not provide sufficient guidance for one skilled in the art to practice the claimed invention without undue experimentation. The disclosure that tissue-specific expression of a single plant cyclin-dependent kinase inhibitor (ICK1) in petal and stamen primordia inhibits floral development, and the disclosure that constitutive expression of three plant cyclin-dependent kinase inhibitors (ICK1, ICN2 and CDKICr) results in decreased ploidy in mature leaves does not provide the guidance required to determine which among the numerous plant cyclin-dependent kinase inhibitors to express, or the guidance required to determine which among the numerous plant promoter sequences to use for expression, in order to obtain transgenic plants in which any undefined aspect of development of any differentiated tissue is inhibited in any unspecified manner. One skilled in the art would have to resort to testing every combination of plant cyclin-dependent kinase inhibitor and plant promoter in order to determine which combination, if any, would result in a specific phenotypic effect. While such trial and error testing would employ techniques that are within the abilities of the skilled artisan, such trial

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and error testing constitutes under experimentation in the absence of guidance for discriminating between operative and inoperative embodiments that fall within the scope of the claims.

Claims 1, 2, 4, 14, 18, 22 and 27 remain rejected, and claim 32 is rejected, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains rejected, and newly added claim 32 is rejected, as being indefinite in the recitation of "development" of a plant, for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn as the term "development" is defined in the specification at page 6 (reply page 11).

The rejection is maintained as the definition of "development" in the specification at page 6 does not specifically limit the term "development" in the rejected claim.

Claims 1, 18, 22 and 27 remain rejected, and newly added claim 32 is rejected, as being indefinite in the recitation of "a differentiated tissue", for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

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Applicant argues that the rejection should be withdrawn as all differentiated tissues are contemplated, and claim breadth is not to be equated with indefiniteness (reply page 11).

The rejection is maintained, as the claimed method does not produce a plant in which the development of all differentiated tissues is inhibited.

Claim 2 remains rejected as being indefinite in the recitation of "homologous to", for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn as the term "homologous to" is defined in the specification at pages 12-15 (reply pages 11-12).

The rejection is maintained as the definition of "homologous to" in the specification at pages 12-15 does not specifically limit the term "homologous to" in the rejected claim.

Claim 4 remains rejected as being indefinite in the recitation of "optimally aligned", for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn as the optimal alignment of sequences is described in the specification at pages 13-14 (reply page 12).

The rejection is maintained as the definition of "optimally aligned" in the specification at pages 13-14 does not specifically limit the term "optimally aligned" in the rejected claim.



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Claim 14 remains rejected as being indefinite in the recitation of "altered", for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn as all petal alterations are contemplated, and claim breadth is not to be equated with indefiniteness (reply page 12).

The rejection is maintained, as the claimed method does not produce a plant in which all petal characteristics are altered. Altered also remains a relative term that lacks a comparative basis.

Claim 27 remains rejected as being indefinite in the recitation of "to change the ploidy", for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn as any aneuploidy is contemplated (reply page 13).

The rejection is maintained, as the claimed method does not produce a plant in which all types of aneuploidy occur. "Change" also remains a relative term that lacks a comparative basis.

Claim 32 is rejected as being indefinite in the recitation of "decreases", as "decreases" is a relative term that lacks a comparative basis.

***Claim Rejections - 35 USC § 102***

Claims 1, 8, 9, 15, 18 and 20-21 remain rejected, and newly submitted claims 30 and 32 are rejected, under 35 U.S.C. 102(b) as being anticipated by John (U.S. Patent Number 5, 750, 862, May 12, 1998), for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed August 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the cited patent cannot anticipate the present claims because the WEE-1 and MIK-1 genes are identified as being from fission yeast, and therefore are not plant cyclin-dependent kinase inhibitors (reply page 13).

The Office maintains that the rejected claims are not limited to cyclin-dependent kinase inhibitor polypeptides of plant origin, as the rejected claims recite no structural limitations that distinguish "a plant cyclin-dependent kinase inhibitor polypeptide" or "an *Arabidopsis* cyclin-dependent kinase inhibitor polypeptide" from other cyclin-dependent kinase inhibitor polypeptides. Since a yeast WEE-1 or MIK-1 polypeptide would inhibit a plant cyclin-dependent kinase, the cited patent anticipates the present claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

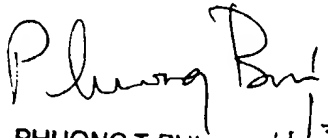
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
November 3, 2003

  
PHUONG T. BUI  
PRIMARY EXAMINER  
11/3/03